

RESPONSE TO OFFICIAL ACTION OF AUGUST 14, 2006**I. Status of the Claims**

Claims 1, 2, 4, 6-8, 10-12, 14, 15, and 18-23 were pending in the case at the time of the Official Action dated August 14, 2006 (“Action”). The Action maintained the rejection of all claims under 35 U.S.C. § 103(a) as being unpatentable over Brodack et al. (U.S. Patent No. 5,560,901).

II. Rejection Based on Brodack et al Under 35 U.S.C. § 103(a) is Overcome

Claims 1, 2, 4, 6-8, 10-12, 14, 15, and 18-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Brodack, maintaining the reasons of record in the office action mailed 12/29/05. The Action found Applicant’s arguments set forth in the Response to the 12/29/05 office action, filed May 1, 2006 (“Response”), unpersuasive for the following reasons. First, the Action argues that the “incorporation of the phrase ‘a coprecipitate of’ is more of a product-by-process type of limitation.” Action, p. 2. Second, the Action argues that “a ‘precipitate’ is small particles that have settled out of a liquid or gaseous suspension by gravity, or that result from a chemical reaction.” Action, pp.2-3. The Action provide no further guidance other than these two statements, and concludes: “Therefore, since the prior art discloses the product, the claim limitations are met.” Action, p. 3.

Once again, Applicant respectfully traverses this rejection because Brodack does not disclose particles comprising a coprecipitate of a metal and one or more radioactive isotopes, and the conclusory statements offered by the Action do not present any evidence that Brodack discloses a product that meets each and every limitation of the claimed subject matter. Although Applicant carefully explained that Brodack does not disclose or suggest the presently claimed subject matter, and in fact teaches away from such particles, the Action maintains the rejection. In order to establish a *prima facie* case of obviousness, the reference(s) must teach or suggest all the claim limitations. MPEP §§ 2142 and 2143. Brodack clearly does not disclose each and every limitation of the pending claims, and therefore maintaining the present rejection is improper for at least this reason.

In response, Applicant submits herewith a declaration by David J. Yang, Ph.D. (“Yang Decl.”), who has worked in the field of Nuclear Medicine for 20 years. In the declaration, Dr. Yang states that in his opinion, “Brodack et al. does not disclose particles comprising a coprecipitate of a metal and one or more radioactive isotopes, and nowhere does Brodack et al. suggest producing a coprecipitate of a metal and one or more radioactive isotopes.” Yang Decl., para. 9. This declaration was not submitted earlier because in the previous Response, Applicant fully explained why one of skill in the art would not understand Brodack to disclose particles comprising a coprecipitate of a metal and one or more radioactive isotopes. Therefore, Applicant did not realize that such a declaration would be necessary to demonstrate the understanding of one of skill in the art, and overcome this rejection. Since the Action does not accept Applicant’s arguments, and presents only conclusory reasoning to reject Applicant’s arguments, Applicant now submits herewith this declaration to show the understanding of one of skill in the art who has practiced for 20 years in the field of Nuclear Medicine, and to refute the Action’s conclusory response.

In the previously filed Response, Applicant thoroughly explained the surprising features of the coprecipitate of a metal and one or more radioactive isotopes disclosed in the present application, for example that coprecipitation can concentrate the radioactive isotopes up to 100 fold in the particles generated, which allows for the production of therapeutic radiopharmaceutical macroaggregate compositions in sufficiently small volumes for practical use. Dr. Yang states that he is surprised by these unexpected advantages of a coprecipitate of a metal and one or more radioactive isotopes. Yang Decl., para. 10. Dr. Yang also confirms that the coprecipitates presently claimed are different than the compositions disclosed in Brodack, “in which the molecules themselves are manipulated to generate the disclosed compositions, for example by the activation of multiple organic moieties.” *Id.* Dr. Yang also confirms that the methods for preparing radionuclide labeled particles disclosed in Brodack are not prepared by aggregation, which is another factor that

distinguishes Brodack from the pending claims. *Id.* at para. 11. Applicant refers to the previously filed Response to explain the basis for Dr. Yang finding that the presently claimed coprecipitates are different than the compositions disclosed in Brodack, as well as a description of the two methods for preparing radiation synovectomy agents actually disclosed in Brodack. Response, pp. 7-8.

In maintaining the rejection over Brodack and rejecting Applicant's arguments, the Action presents an incredibly broad definition of "precipitate" (which is not a term that even appears in the examined claims), arguing that a "precipitate" is small particles "that result from a chemical reaction." Although the Action does not explain its reasoning, it appears to suggest that based on this definition, any reference that discloses a metal and one or more radioactive isotopes in a chemical reaction renders the presently claimed subject matter obvious. This definition offered by the Action for "precipitate" is not the definition of this term as generally understood by scientists. Yang Decl., para. 8. If the Action insists on maintaining the rejection for this reason, Applicant respectfully requests a scientific publication demonstrating any adoption of the broad definition suggested by the Action, in particular for the term "coprecipitate," which is the term that appears in the pending claims.

As confirmed by the declaration of Dr. Yang, one of skill in the art who has practiced for 20 years in the field of Nuclear Medicine, Brodack does not disclose particles comprising a coprecipitate of a metal and one or more radioactive isotopes, does not disclose or suggest the method of coprecipitation or the generation of coprecipitates, and in fact teaches away from such aggregation compositions. Therefore, Brodack cannot establish a *prima facie* case of obviousness of the presently pending claims because it does not teach or suggest the claimed subject matter, does not create any reasonable expectation that the claimed subject matter would work, and does not teach or suggest all of the claim limitations.

III. Publication information

The Action requested the publication dates for References C4 and C33. Reference C4 was published March 23, 1964. Reference C33 was published at the Buet-Unu International Workshop on Technologies for Arsenic Removal from Drinking Water held May 5-7, 2001, in Dhaka, Bangladesh, India.

CONCLUSION

It is Applicant's belief that the claims are in condition for allowance. Such favorable action is respectfully requested. If the Examiner has any questions or comments regarding any issue associated with this application a telephone call to the undersigned representative at 512.542.8569 is welcome.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Margaret Sampson", with a stylized, flowing script.

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Date: October 16, 2006